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Aneas

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(54) **DEVICE FOR CONNECTION BETWEEN A RECIPIENT AND A CONTAINER AND READY-TO-USE ASSEMBLY COMPRISING SUCH A DEVICE**

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(21) Appl. No.: **09/497,475**

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(30) **Foreign Application Priority Data**

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(51) Int. Cl.<sup>7</sup> ..... **A61B 19/00; A61M 5/32**

(52) U.S. Cl. .... **604/411; 604/86; 604/414; 604/415; 215/247**

(58) Field of Search ..... **604/403, 411, 604/414, 415, 86-89, 200, 201, 905; 215/247, 249, DIG. 3; 222/83**

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Primary Examiner—David J. Walczak

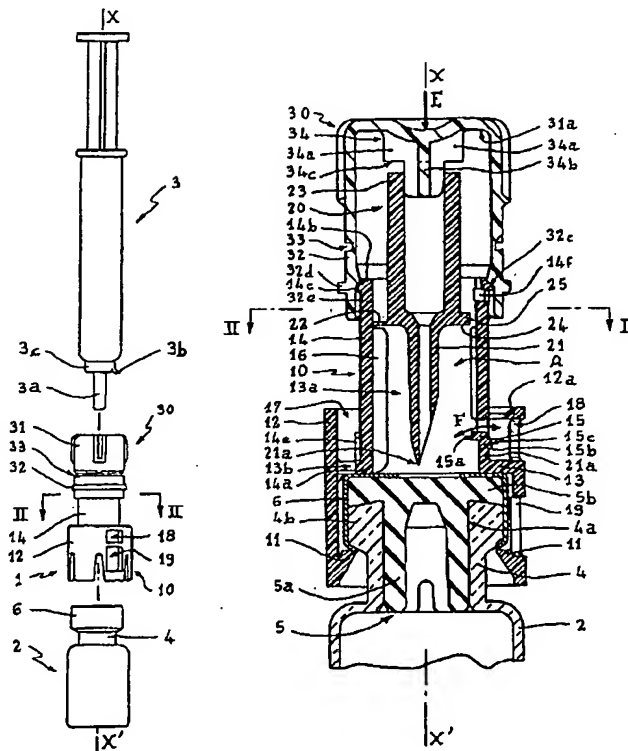
Assistant Examiner—Tuan Nguyen

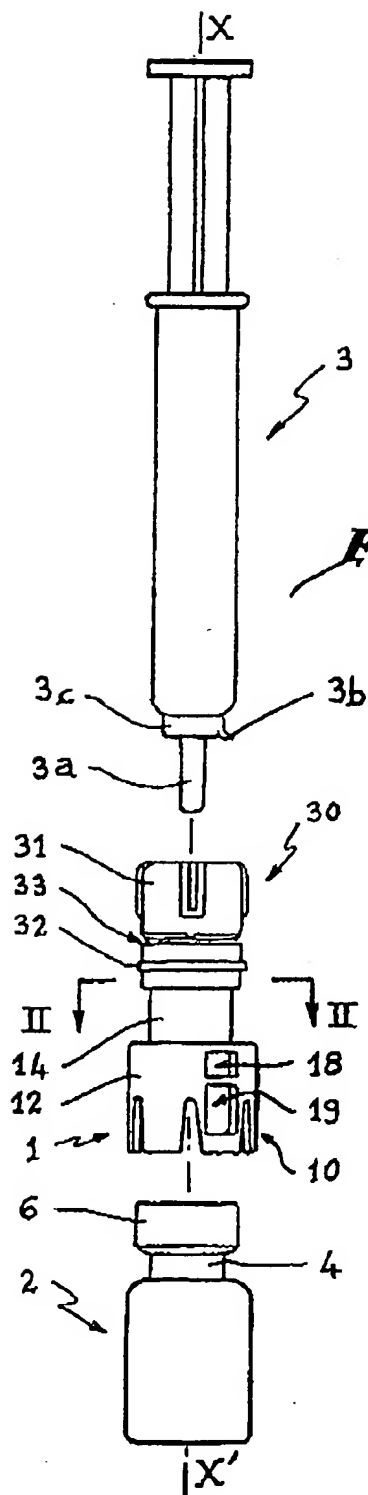
(74) Attorney, Agent, or Firm—Olliff & Berridge, PLC

(57) **ABSTRACT**

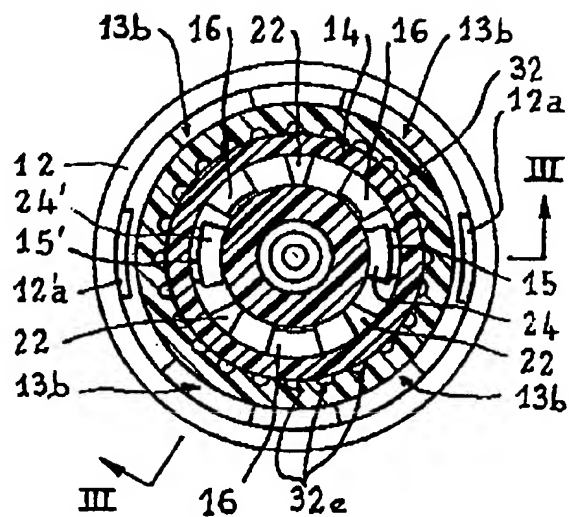
A device for connecting between a recipient and a container, including a base, mounted on the recipient and a bush forming an inner bore, and a plunger adapted to slide in this bore, between a first position disengaged with respect to the stopper of the recipient and a second, so-called transfer position, in which a hollow needle borne by the plunger traverses the stopper. The base is provided with at least one elastic catch for retaining the plunger in the transfer position, this catch projecting, from the bush, towards the interior of the bore and being adapted to cooperate with an outer radial tab of the plunger.

**13 Claims, 4 Drawing Sheets**

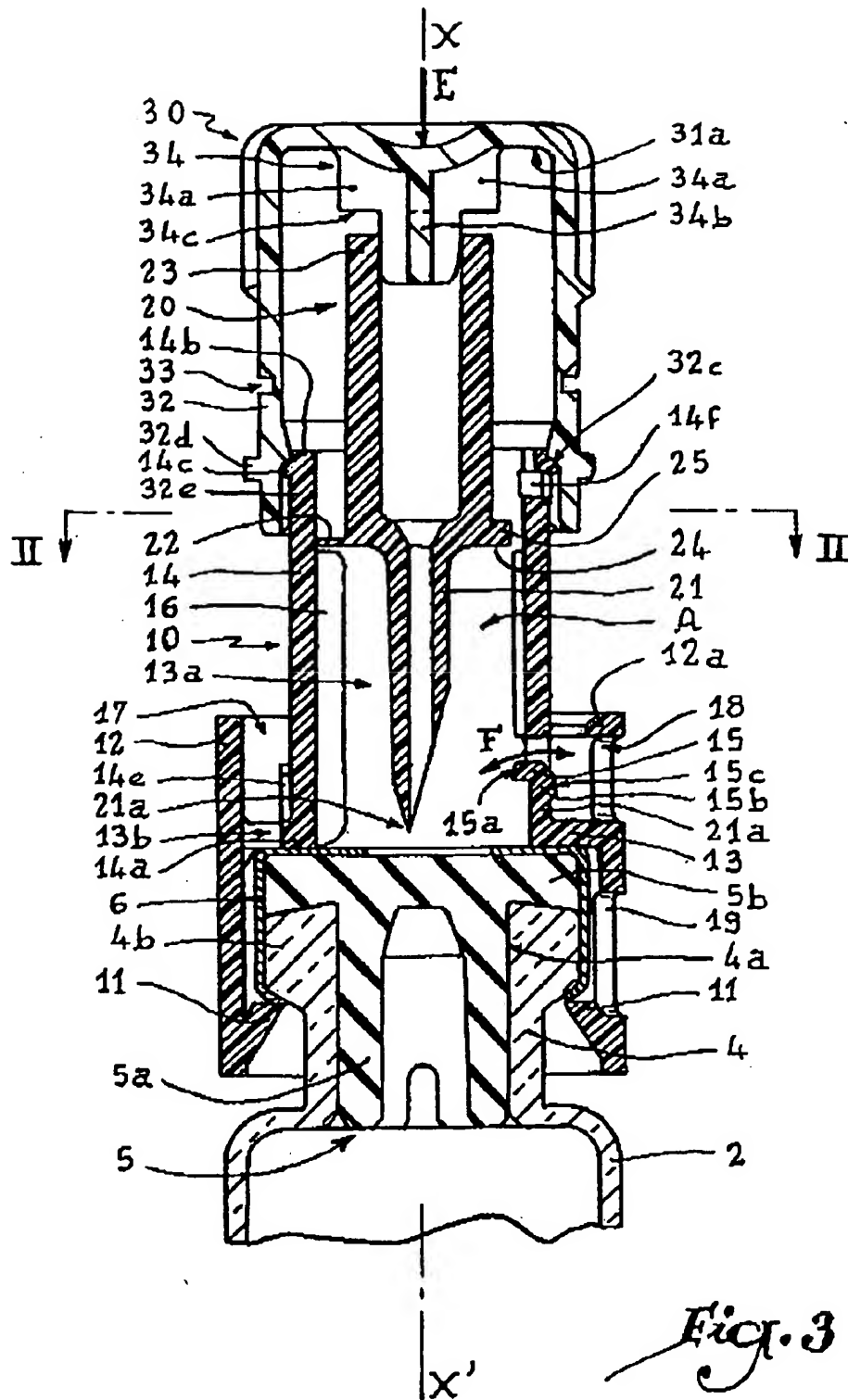


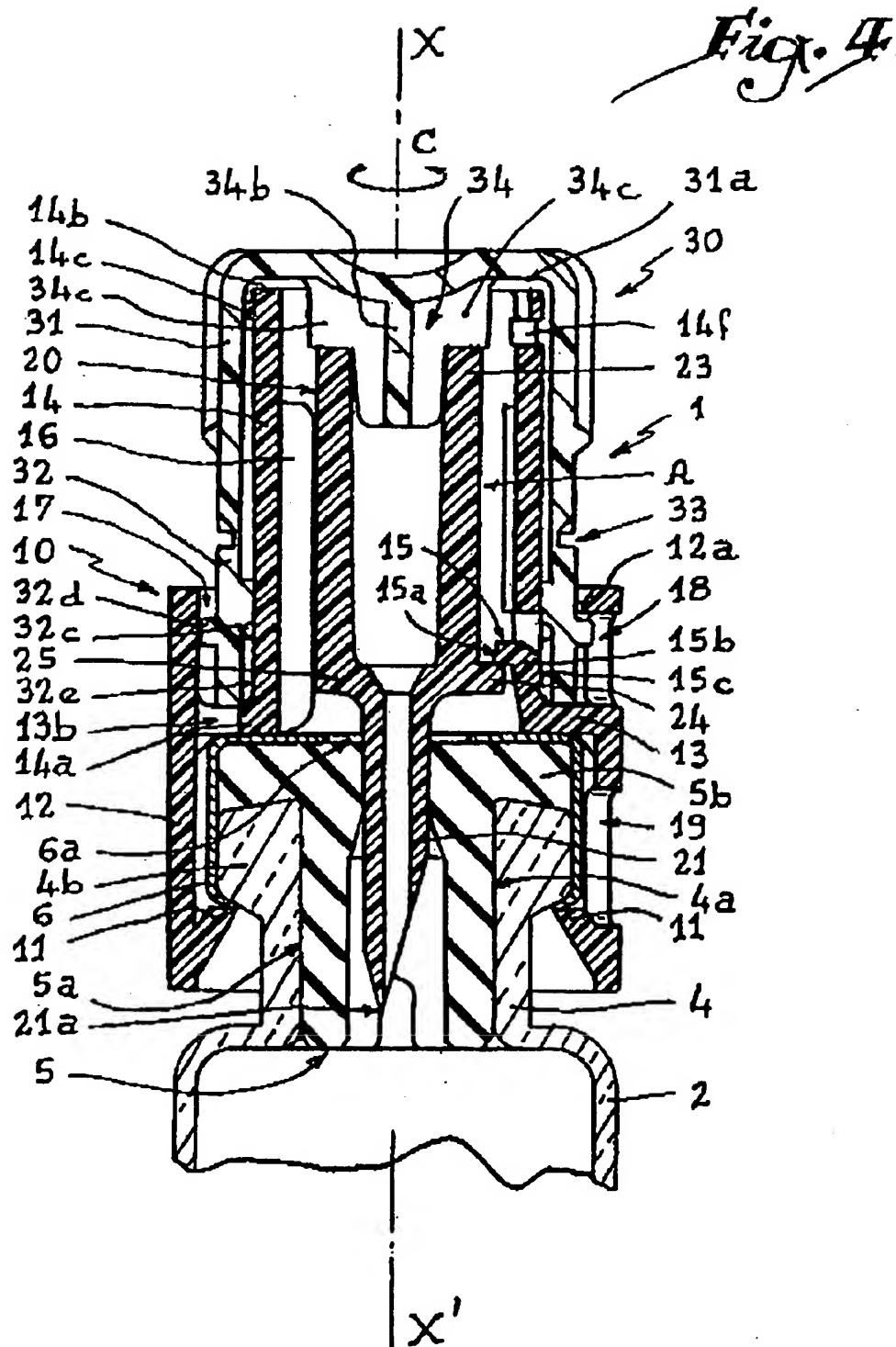


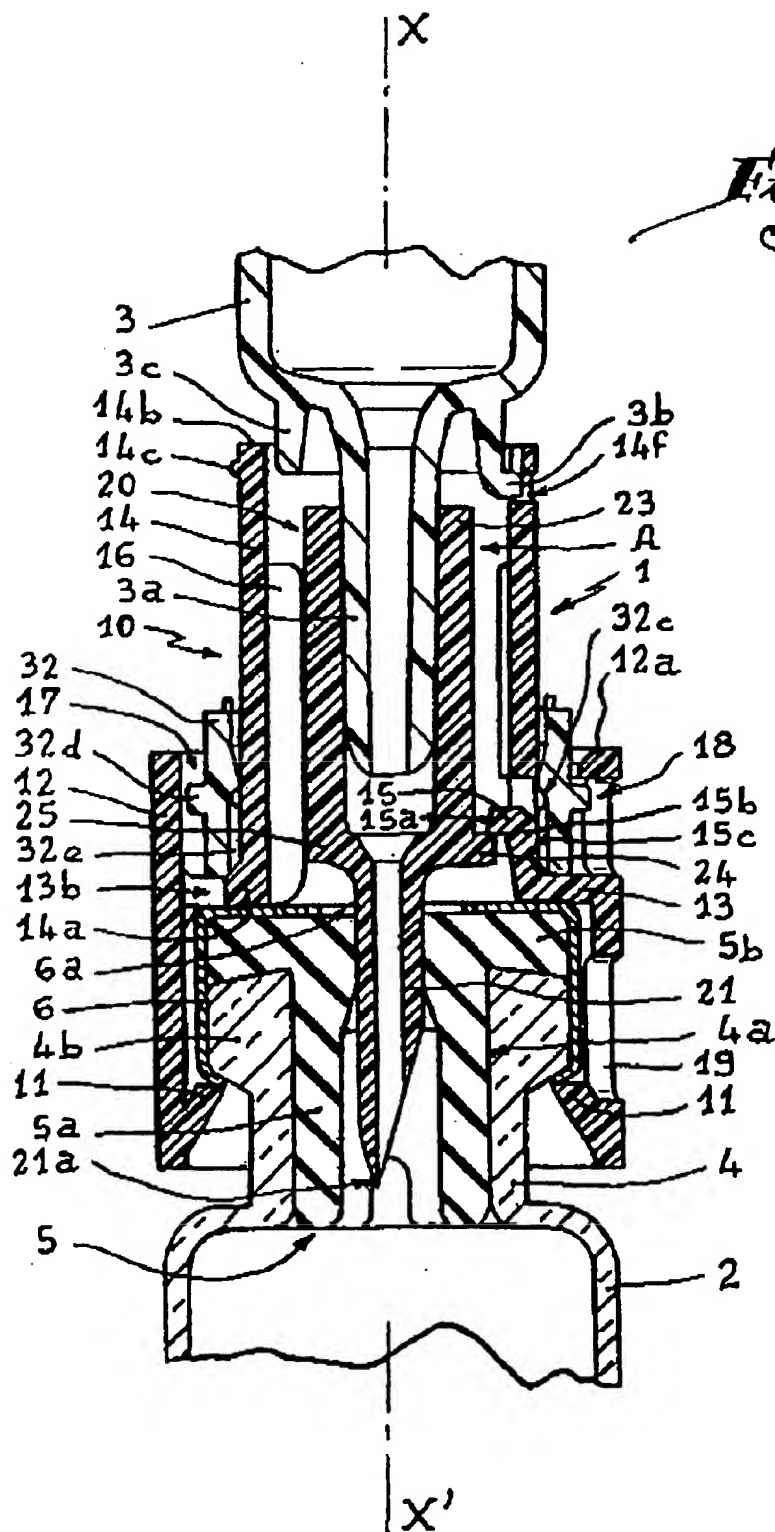
*Fig. 1*



*Fig. 2*

*Fig. 3*





*Fig. 5*

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# DEVICE FOR CONNECTION BETWEEN A RECIPIENT AND A CONTAINER AND READY-TO-USE ASSEMBLY COMPRISING SUCH A DEVICE

## FIELD OF THE INVENTION

The present invention relates to a device for connection between a closed recipient and a container, and to a ready-to-use assembly comprising, inter alia, a closed recipient and a connection device of the afore-mentioned type.

## BACKGROUND OF THE INVENTION

In the domain of packaging medicines, it is known to store one component of a pharmaceutical preparation, such as for example its active ingredient, in a recipient closed by a relatively non-rigid material, for example made of elastomer. A liquid may be introduced into this recipient, after perforation of the stopper, in order to place the component contained in the recipient in solution or in suspension, so as to obtain a preparation, in particular a medicament or vaccine, in liquid form ready to be administered to the patients.

Documents WO-A-90/03536 and WO-A-97/10156 disclose connection devices, each comprising a base adapted to cover the neck of a recipient and extended by a flange or bush forming an inner bore, while a plunger is mounted to slide in this bore. The plunger is provided to be pushed towards a transfer position in which a hollow needle borne by the plunger passes through the stopper of the recipient. These known devices allow axial movements of the plunger when it has been displaced up to transfer position, which might lead to leakages and does not efficiently control the lost volume of the recipient, i.e. the quantity of liquid which cannot be drawn off therefrom.

Document WO-A-98/13006 discloses a device adapted, in particular, for connection between a recipient with a stopper which is adapted to be perforated and a syringe, in which teeth are distributed about the axis of the plunger and provided to be returned centrifugally or centripetally in order to cooperate with a stop element provided on a base. This device allows a locking of the plunger as long as the effort of displacement to which it is subjected is not too great. However, under certain conditions, the teeth might be deformed plastically, which might allow the plunger to tear in a direction of extraction.

It is a particular object of the present invention to overcome these drawbacks, by proposing an unproved connection device in which a particularly efficient locking of the plunger in transfer position is obtained

## SUMMARY UP THE INVENTION

To that end, the invention relates to a device of the type mentioned above, in which the base is provided with at least one elastic catch for retaining the plunger in transfer position, this catch projecting from the bush towards the interior of the bore and being adapted to cooperate with an outer radial tab of the plunger.

Thanks to the invention, the elastic catch guarantees a efficient locking of the plunger in transfer position. Such locking is all the more efficient as a plurality of catches are advantageously provided, which may be regularly distributed about the central axis of the device.

According to a first advantageous aspect of the invention, the catch is provided, on an outer radial face, with a heel

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adapted to cooperate with a ring for locking the plunger in position of retention, this ring being adapted to slide about the bush. This ring gives the retaining catch a sufficient rigidity to efficiently resist an effort of displacement of the plunger from the transfer position. This ring is advantageously provided with an outer radial flange for locking in translation in a position of cooperation with the catch.

According to another advantageous aspect of the invention, the device comprises means for locking in rotation the plunger and/or the locking ring. These means advantageously comprise longitudinal ribs made on the inner face and/or the outer face of the bush and adapted to cooperate with corresponding elements in relief provided on the outer radial surface of the plunger and/or on the inner radial surface of the ring.

According to another advantageous aspect of the invention, in disengaged position with respect to the stopper, the plunger is fast with the bush by at least one breakable tongue. In addition, the base and the plunger are advantageously formed in one piece by injection of plastics material. This facilitates positioning of the plunger with respect to the base, insofar as this positioning results directly from the method of manufacture and as it is not necessary to provide an assembly step corresponding to the insertion of the plunger in the base. Moreover, the one-piece nature of the base and plunger guarantees that the plunger does not risk sliding in the bore, particularly under the effect of vibrations or sudden accelerations during transport of the device. In this way, the tip of a needle borne by the plunger is held for certain inside the bore, with the result that it does not risk projecting beyond the base to the point of marking or perforating a stopper when the device is positioned on the recipient. With the known devices, such a risk could not be completely eliminated, including when using beads for holding the plunger.

According to another advantageous aspect of the invention, a cap for protecting the bore and the plunger is provided, on an inner face, with a member for transmission of a thrust effort for the displacement of the plunger from the first position towards the second position. In this way, the protecting cap serves as member for maneuvering the plunger.

According to another advantageous aspect of the invention, the bush comprises, near its free edge, means for blocking the container by cooperation of shapes, in particular bayonet-type locking slots adapted to cooperate with at least one tab of the container.

According to another advantageous aspect, the base comprises a cylindrical surface defining a skirt which extends around the neck of the recipient and bears hooking teeth, this skirt comprising at least one opening far access to the catch and/or to certain hooking teeth from the outside. These openings are particularly useful for efficiently moulding the catch or catches and the corresponding teeth.

The invention also relates to a ready-to-use assembly comprising a closed recipient containing a product, in particular a pharmaceutical preparation, this recipient being provided with a neck whose opening is occluded by a stopper, and a connection device as described hereinabove, mounted on the recipient. Such an assembly enables a component of a medicine or a vaccine, in particular its active ingredient, to be kept sterile and to be prepared when necessary by mixture with a liquid, while its plunger is efficiently held in position.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more readily understood in reading the following description of an embodiment of a connection

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device in accordance with its principle, given solely by way of example, with reference to the accompanying drawings, in which:

FIG. 1 is an exploded side view of a ready-to-use assembly according to the invention.

FIG. 2 is a transverse section along line II—II of FIG. 1.

FIG. 3 is a broken section along line III—III in FIG. 2, the plane of section of FIG. 2 being indicated at II—II.

FIG. 4 is a section similar to FIG. 3 during a fast step of using the device, and

FIG. 5 is a section similar to FIG. 3 during a second step of using the device.

#### DESCRIPTION OF PREFERRED EMBODIMENT

Referring now to the drawings, the device according to the invention has a dual function. On the one hand, it guarantees the tamper-proof nature of a recipient 2, for example a glass bottle containing a product (not shown) and previously closed or stopped. This product may be a powder intended to form a drinkable vaccine, or it may be question of any other type of pharmaceutical preparation, in particular any type of medicine. On the other hand, the device 1 ensures or establishes a tight connection between the interior of the recipient 2 and the interior of another container 3, such as a syringe containing a liquid intended to place the product contained in the recipient 2 in solution or in suspension. Instead of a syringe, the container 3 might be formed by a supple bag or another glass bottle.

The recipient 2 comprises a neck 4, whose opening 4a is tightly obturated by a clapper 5 made of a relatively non-rigid material, for example elastomer and, in particular, rubber. The neck 4 comprises an outer annular bead 4b on which is crimped a capsule 6 which also covers a peripheral part of the stopper 5 and which is provided with a central opening 6a through which it is possible to perforate the stopper 5. The stopper 5 comprises a substantially cylindrical central part 5a, adapted for supple and tight fit inside the opening 4a, and a flattened outer part 5b, shouldered by the bead 4a, and covered by the capsule 6.

The device 1 is essentially formed by two parts made by injection of plastics material, for example polyethylene, polypropylene, polyamide or ABS (polyacrylonitrile/butadiene/styrene), namely a base element 10 intended to be mounted around elements 4 to 6, and a cap 30.

The base element 10 comprises a plurality of hooking teeth 11 provided to be arranged around the bead 4b, as shown in FIG. 3. These teeth are defined in the lower part of a cylindrical skirt 12 surrounding the neck 4. The element 10 comprises a wall 13 for abutment on the upper part of the capsule 6, this wall being provided with a central recess 13a bordered by a cylindrical bush 14, concentric to the skirt 12 and extending opposite the wall 13 with respect to said skirt.

XX' denotes the central axis of the device 1 which is, in particular, the axis of the skirt 12 and of the bush 14. The bush 14 extends up to contact with the capsule 6 and defines a bore A centred on axis XX'.

In its part 14a closest to the stopper 5, the bush 14 is equipped with two catches 15 and 15' projecting radially towards the interior of the bore A. Taking into account the plastic material used for moulding element 10, these lips are supple enough to be elastically deformed, as represented by arrow F in FIG. 3.

As is clearly visible in FIG. 2, the catches 15 and 15' are diametrically opposite. However, other distributions, as well as a different number of retaining catches, may be envisaged.

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Inside bore A is disposed a plunger 20 forming a hollow needle 21 adapted to perforate the stopper 5 in its central part. Plunger 20 is connected to the bush 14 by tongues 22 which are three in number and regularly distributed on the periphery of the plunger 20. In this way, the plunger 20 is in one-piece with the base 10 until the tongues 22 are broken.

Plunger 20 also forms a sleeve 23 for receiving the nose 3a of the syringe 3. The inner diameter of the sleeve 23 is chosen to be sufficiently small for only those syringes that may be introduced therein to correspond to a special manufacture intended for this use.

Plunger 20 bears two tabs 24 extending radially outwardly at the level of the transition zone 25 between the needle 21 and the sleeve 23.

On its inner radial surface, the bush 14 bears three longitudinal ribs 16 which cooperate with the sides of the tabs 24 to avoid a rotation of the plunger 20 about axis XX'.

The cap 30 is formed by a removable part 31, surrounding the free edge 14b of the bush 14, and by a ring 32 disposed around the bush 14, parts 31 and 32 being connected by a breakable zone 33.

Near its free edge 14b, the bush 14 is provided with an outer ring 14c provided to penetrate in an inner peripheral groove 32c of the ring 32. These outer ring and groove make it possible to maintain the cap 30 in position with respect to the element 10 in the storage position of FIGS. 1 to 3. The device 1 may be maintained in position on bottle 2 for several months, before use.

On its inner face 31a, part 31 is equipped with an extension 34 whose shape is adapted to be able to engage partially in the sleeve 23. In cross-section, this extension is in the form of a cross, as it is formed by two substantially orthogonal ribs 34a and 34b intersecting at the level of axis XX'. In the position of FIG. 3, the positioning of extension 34, and in particular its depth of penetration in sleeve 23, is determined by the cooperation of the ring 14c and the groove 32c.

When it is necessary to mix the contents of syringe 23 and of recipient 2, an effort, represented by arrow E in FIG. 3, is exerted on part 31 of the cap 30, which has the effect of bearing the shoulders 34c of the ribs 34a and 34b against the free edge of the sleeve 23, while driving groove 32c with respect to ring 14c. Ring 32 then moves along the bush 14 in the direction of wall 13. The effort transmitted by the extension 34 to the sleeve 23 has the effect of cutting the tongues 22 and of pushing the plunger 20 towards the central opening 6a of the capsule 6, with the result that the sharp tip 21a of the needle 21 penetrates in the bottle 2 through the stopper 5. Effort E is maintained until the ring 32 is received in an annular space 17 defined between the upper part of the skirt 12 and the lower part 14a of the bush 14. Such displacement of the ring 32 corresponds to a displacement of the plunger 20 such that the transition zone 25 between the needle 21 and the sleeve 23 is disposed in the immediate vicinity of the upper surface of the capsule 6.

Such displacement of the plunger 20 has the effect of engaging the tabs 24 and 24' respectively to the rear of the catches 15 and 15', these catches being driven radially, outwardly of the bush 14, by tabs 24 and 24' during the movement of advance of the plunger 20. This is possible, as the front face 15a of the catch 15 visible in FIGS. 3 to 5 is inclined with respect to axis XX'. In that case, one is in the position of FIG. 4 where the ring 32 exerts on a heel 15b, located on a rear or outer radial surface 15c of the catch 15, a centripetal effort which maintains the catch 15 in an efficient locking position of the tab 24. Catch 15' which is identical, functions in the same way.

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In order to guarantee a constant positioning of the ring 32 inside the volume 17, this ring is provided with an outer flange 32d adapted to engage beneath an upper re-entrant edge 12a of the skirt 12 provided on an angular sector at the level of catch 15. A similar re-entrant edge 12'a is provided at the level of catch 15'.

In this way, the ring 32 is firmly maintained in a position such that it prevents an elastic deformation of the catch 15 which might allow a movement of the tabs 24 in a direction moving away with respect to the stopper 5. Functioning is similar at the level of catch 15'.

At the level of its part 14a, the bush 14 is provided with outer ribs 14e provided to engage in corresponding notches 32e made on the inner radial surface of the ring 32. In this way, in the position of FIG. 4, the ring 32 is immobilized in rotation about axis XX'. It is then possible to exert on part 31 of the cap 30 a couple 3, allowing the breakable part 33 to be broken so as to withdraw this part 31, while the ring 32 remains in position of locking of the catches 15 and 15'.

The nose 3a of the syringe 3 is then introduced in the sleeve 23, as shown in FIG. 5, using one or more tabs 3b provided at the level of a base bush 3c of the syringe 3 in order each to penetrate in a bayonet-type locking slot 14f provided near the free edge 14h of the bush 14. This particular construction allows an efficient locking of the syringe 3 with respect to the device 1 during the operations of transit of the liquid front the syringe towards the bottle and of recovery of the preparation in the syringe.

The bush 12 is provided at the level of catch 15, with an opening 18 which allows a mobile slide to form the rear part of the catch 15 and the re-entrant edge 12a of the skirt 12 during moulding. The teeth 11 may be obtained during moulding of the element 10 by slides penetrating to the bottom of the skirt 12 through the openings 13b provided in the wall 13. Taking into account the geometry and location of the catch 15, this is not possible for the teeth 11 located in the same angular sector as the catch 15 and 15'. An opening 19 is provided in the skirt 12, below the opening 18, to allow the passage of a mobile slide for forming the corresponding tooth 11 during moulding of the device 1. Corresponding openings are, of course provided in the angular sector corresponding to catch 15'.

The particular structure of the catch 15 and 15' and their cooperation with the ring 32 guarantee an efficient locking of the plunger 20 in the transfer position of FIGS. 4 and 5. It will be readily understood that the number and distribution of the catches 15, 15' or equivalent depend on a choice of design within the scope of the person skilled in the art, as a function of the desired force of locking and of the rigidity of the materials used.

The invention presents the particular advantage; that it is adaptable to bottles packaged conventionally with a stopper and a crimped capsule 6, which allows it to be used after packaging of part of the medicines on a conventional chain.

The invention is applicable independently of the mode of fixing the base element 10 on the recipient 2 and, in general, it can be used in any connection device comprising a plunger mobile inside a bore of a base mounted on a recipient.

What is claimed is:

1. A device for connection between a closed recipient and a container, said closed recipient comprising a neck whose opening is obdured by a stopper, said connection device comprising:

a base adapted to be mounted on said recipient and comprising a bush forming an inner bore,

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a plunger adapted to slide in said bore, between a first position disengaged with respect to said stopper and a second position, in which a hollow needle borne by said plunger traverses said stopper, wherein said base is provided with at least one elastic catch deformable outwards of said bush, said catch projecting from said bush towards the interior of the bore for retaining the plunger in the second position and being adapted to be driven radially outwardly of said bush and substantially external of the bore by an outer radial tab of said plunger, during the movement of said plunger between the first position and the second position, and to lock said tab and said plunger in said second position.

2. The device of claim 1, wherein said catch is provided, on an outer radial face, with a heel adapted to cooperate with a ring for locking said plunger in position of retention, said ring being adapted to slide around said bush.

3. The device of claim 2, wherein said ring is provided with an outer radial flange for locking in translation in a position of cooperation with said catch.

4. The device of claim 1, wherein the device comprises means for locking said plunger in rotation about a central axis of said bore.

5. The device of claim 4 wherein said means for locking in rotation comprise longitudinal ribs made on at least one of the inner face and of the outer face of said bush and adapted to cooperate with corresponding elements in relief provided on the outer radial surface of said plunger or on the inner radial surface of a ring.

6. The device of claim 1, wherein, in said disengaged position with respect to said stopper, said plunger is connected with said bush by at least one breakable tongue.

7. The device of claim 1 wherein said base and said plunger are formed in one piece by injection of plastics material.

8. The device of claim 1, wherein the device comprises a cap for protecting said bore and said plunger, said cap being provided, on an inner face, with a member for transmitting a thrust effort for the displacement of said plunger from said first position towards said second position.

9. The device of claim 1, wherein said bush comprises, near its free edge, means for locking said container with bayonet-type locking slots adapted to cooperate with at least one tab of said container.

10. The device of claim 1, wherein said base comprises a skirt which extends around said neck of said recipient and bears hooking teeth, said skirt comprising at least one opening for access to at least of one said catch or to at least one hooking teeth from the outside.

11. A ready-to-use assembly comprising a closed recipient containing a product, in particular a pharmaceutical preparation, said recipient being provided with a neck whose opening is obdured by a stopper, and the connection device of claim 1 mounted on said recipient.

12. The device of claim 1, wherein the device comprises means for locking a ring with respect to the bush in rotation about a central axis of said bore.

13. The device of claim 12, wherein said means for locking in rotation comprise longitudinal ribs made on at least one of the inner face and outer face of said bush and adapted to cooperate with corresponding elements in relief provided on the outer radial surface of said plunger or on the inner radial surface of said ring.

\* \* \* \* \*



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(12) **United States Patent**  
**Thibault et al.**

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(45) **Date of Patent:** **May 7, 2002**

(54) **PLASTIC CLOSURE FOR VIALS AND  
OTHER MEDICAL CONTAINERS**

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(57) **ABSTRACT**

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**Related U.S. Application Data**

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1998.

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215/274; 215/324; 215/325; 215/DIG. 3;  
604/411; 604/415

(58) **Field of Search** ..... 215/247, 249,  
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296; 222/81, 83, 83.5; 141/2, 25, 26, 27,  
28, 329, 330, 18, 21; 604/403, 406, 411–416;  
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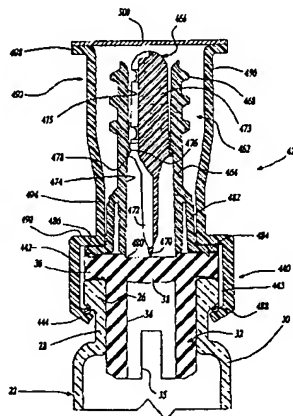
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The plastic closure of this invention is particularly, but not exclusively adapted for sealing medicament vials and other medical containers or as a collar for retaining a fluid transferset on a medical container. The plastic closure of this invention includes a generally tubular portion which surrounds the rim of the container and a free end portion which is permanently radially deformed or crimped into the neck of the container. The plastic closure of this invention is formed of a polymer, preferably a polymeric alloy or melt blend, which is sufficiently malleable to permit radial deformation, yet sufficiently rigid to retain its shape following deformation and sufficiently resistant to creep to maintain the seal between the plastic closure and the container following deformation. A preferred polymer for the plastic closure of this invention is an alloy or melt blend comprising a relatively rigid polymer such as polycarbonate and a soft malleable co-polymer such as a polyester. Where the plastic closure of this invention is used to seal a vial, for example, the closure includes a radial portion overlying the rim portion of the stopper having a central opening and a cup-shaped cap is received over the collar having retainer portions received within the central opening of the cap which may be removed by finger pressure. When the collar of this invention is used to secure a fluid transferset on a vial, the collar includes a proximate tubular portion integral with the radial portion which surrounds at least a portion of the transferset. In one embodiment, the second tubular portion surrounds the entire transferset and the open end is sealed with a peel-off seal and in another embodiment a separate cap surrounds the distal end of the transferset.

**21 Claims, 5 Drawing Sheets**



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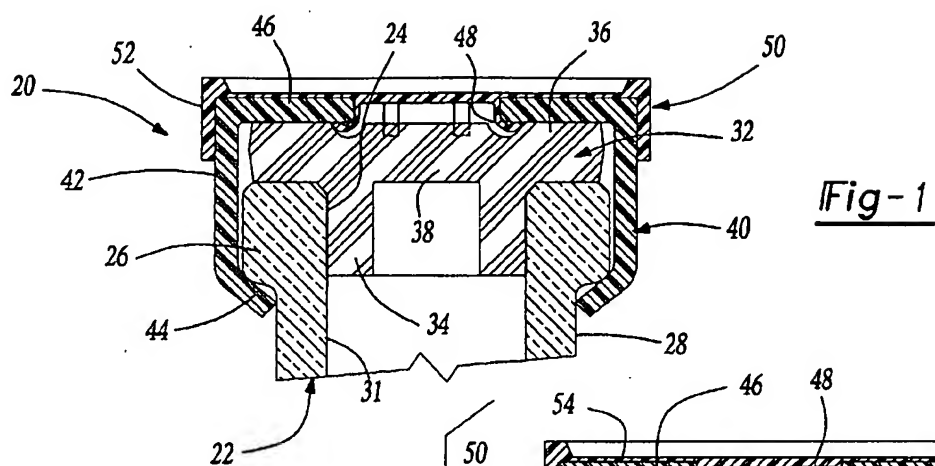
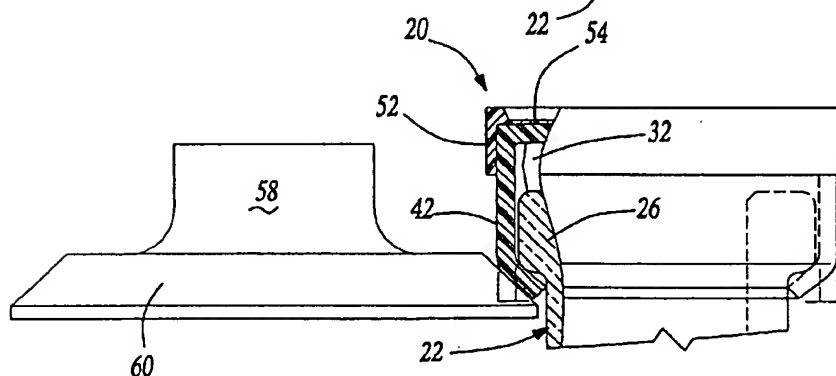
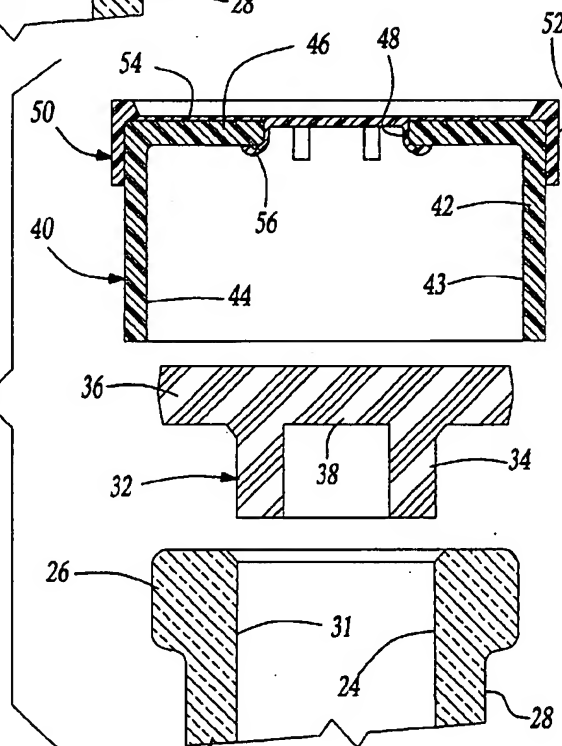
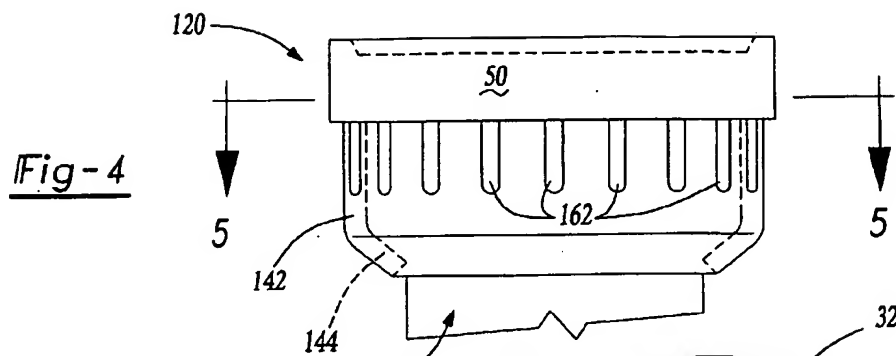
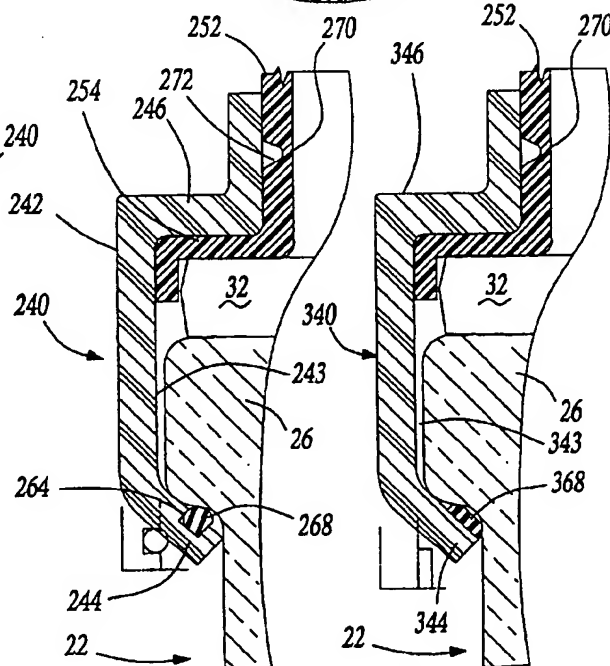
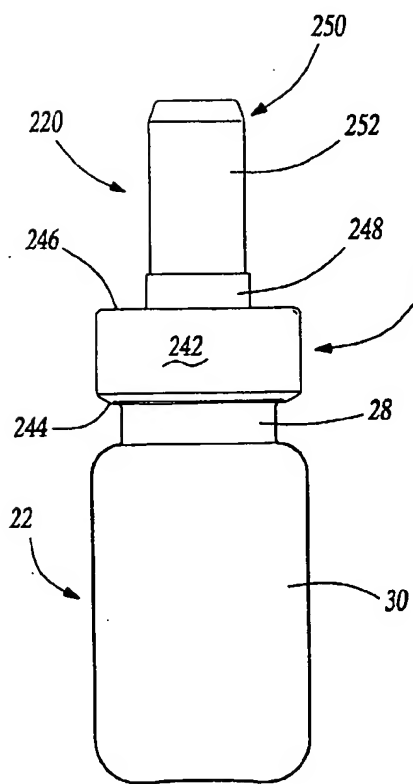
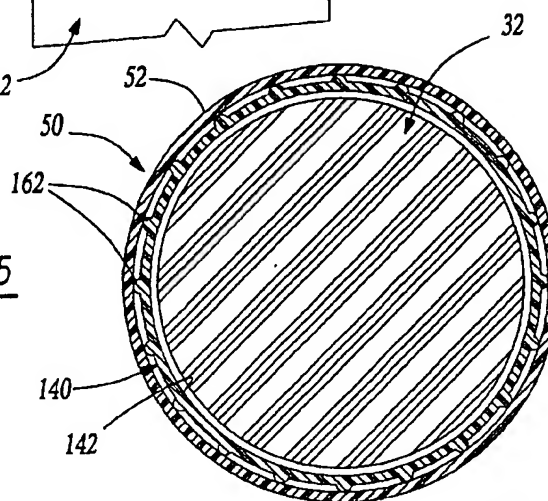


Fig-2





**Fig-5**



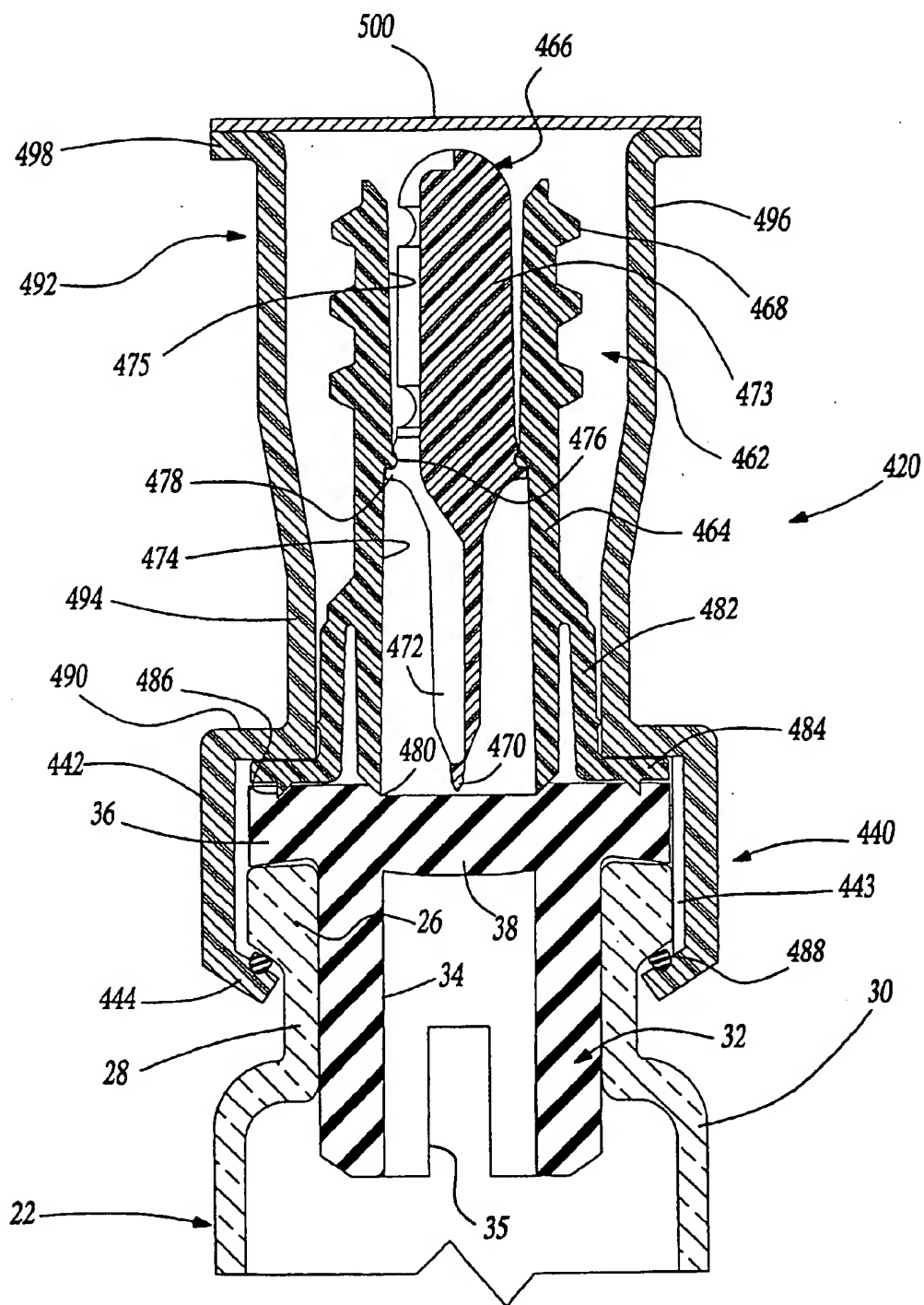


Fig-9

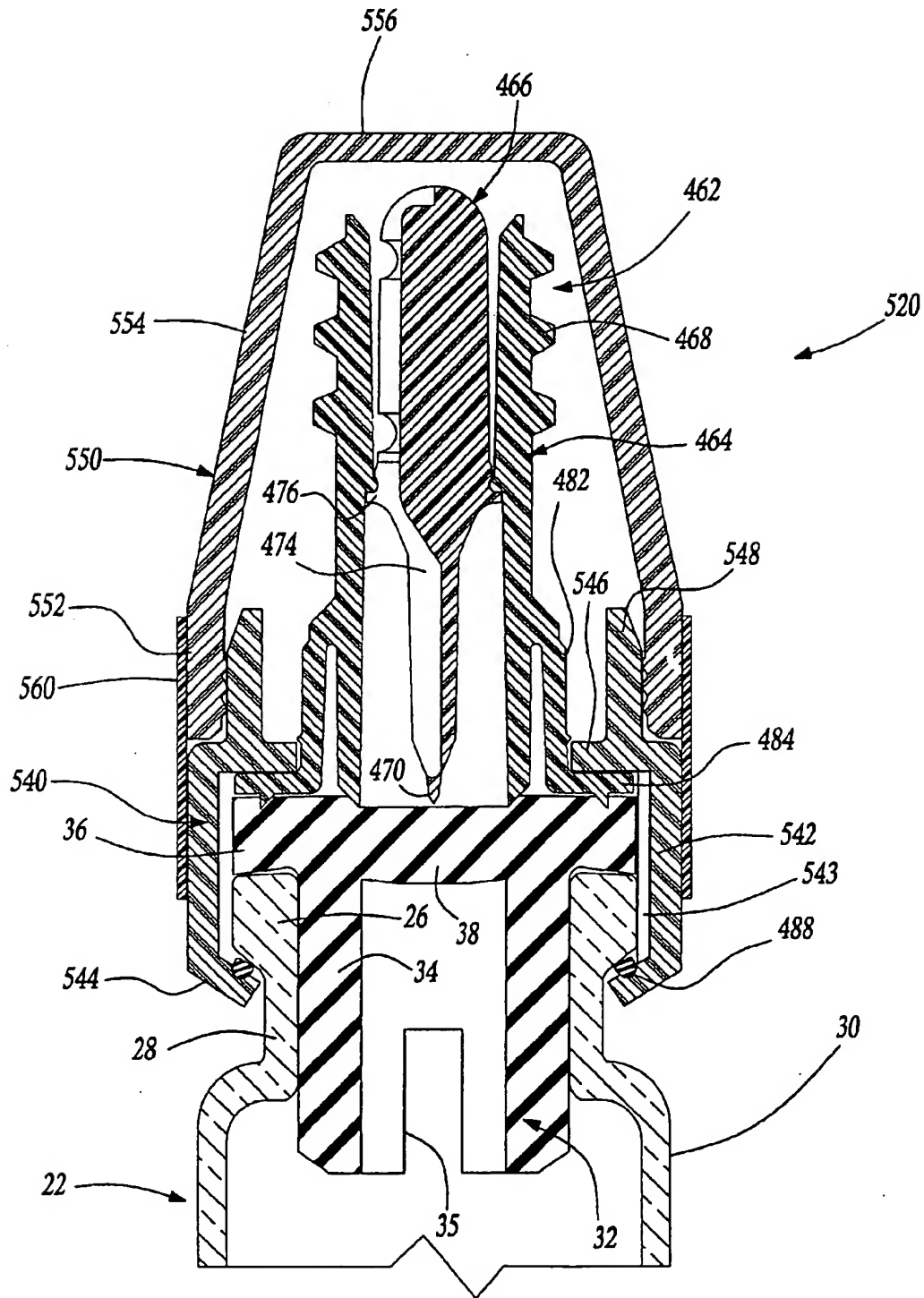
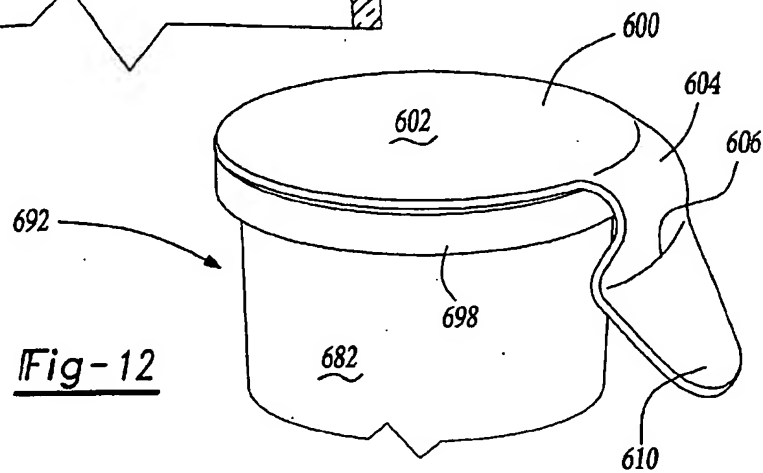
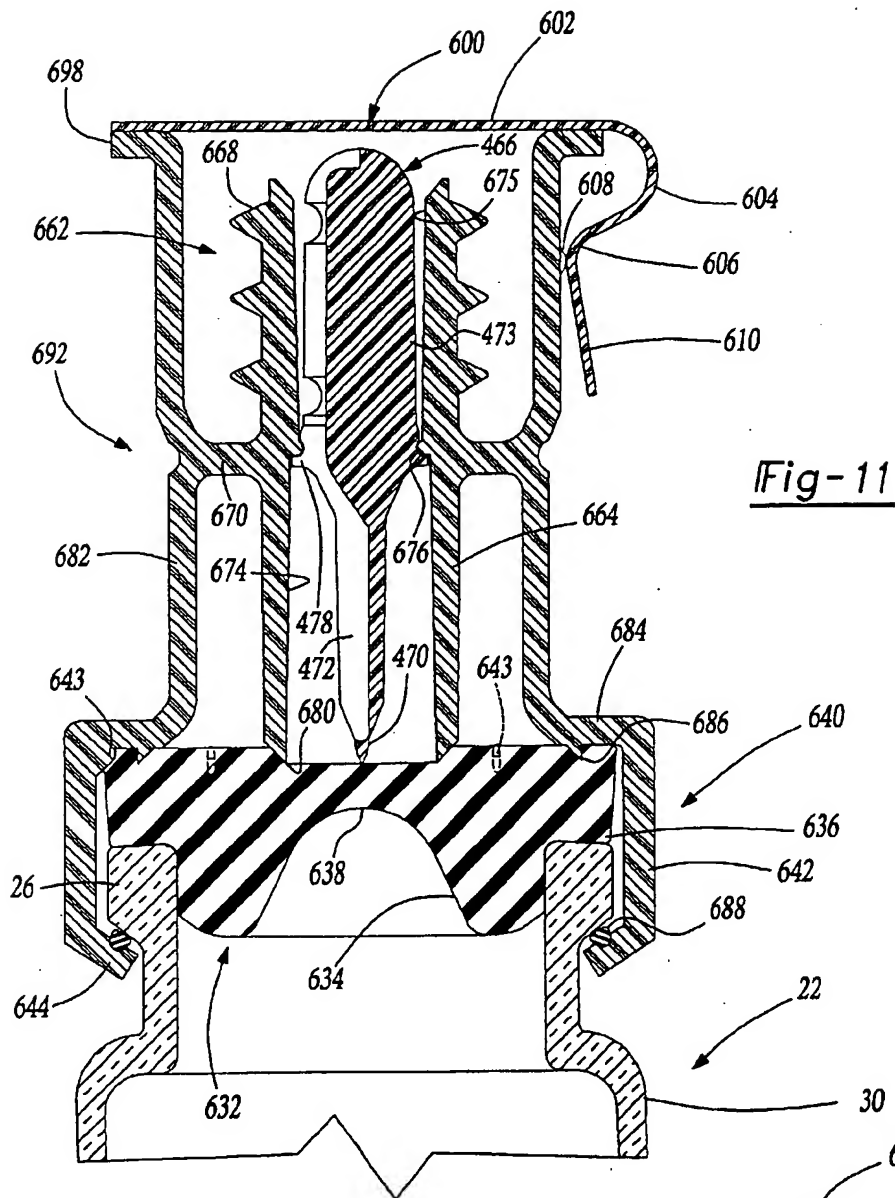


Fig-10



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## PLASTIC CLOSURE FOR VIALS AND OTHER MEDICAL CONTAINERS

This application claims benefit of U.S. application Ser. No. 60/082,382, filed Apr. 20, 1998.

### FIELD OF THE INVENTION

This invention relates to an improved plastic closure such as a cap or collar for closing or sealing containers such as vials containing a medicament which eliminates the problems associated with a malleable metal cap or collar such as aluminum. The plastic closure of this invention may be used as a cap to seal a conventional vial having an elastomeric stopper or as a collar for retaining a fluid transferset separate from or integral with the collar.

### BACKGROUND OF THE INVENTION

It is conventional to store medicament such as drugs in a sealed vial or other container for later use. Such medicaments may be in a dry or powdered form to increase the shelf life of the drugs and reduce inventory space. Such dry or powdered drugs are generally stored in a sealed vial and reconstituted in liquid form for administration to a patient by adding a diluent or solvent. Alternatively, the drug may be in liquid or even gaseous form. A conventional vial for storing medicament generally includes an open end, a radial rim portion surrounding the open end and a reduced diameter neck portion adjacent the rim portion. The vial is conventionally sealed with an elastomeric stopper which generally includes a tubular portion inserted into the neck of the vial and a planar rim portion which overlies the vial rim. The stopper is normally secured to the vial with a thin malleable metal cap, such as aluminum. The aluminum cap includes a tubular portion which surrounds the rim portions of the stopper and vial, an inwardly projecting annular portion which overlies the rim portion of the stopper and a distal end portion which is crimped or deformed radially into the vial neck beneath the vial rim portion. Because aluminum is malleable, the collar accommodates the buildup of tolerances of the dimensions of the stopper and vial rim. The dimensions and tolerances of standard vials and stoppers are set by the International Standards Organization (ISO).

The radial portion of the aluminum cap which overlies the stopper rim portion may be closed, in which case the aluminum cap is removed by "peeling" the aluminum cap from the vial. A pre-slit tab located in the middle area is provided which overlies the vial rim, permitting the cap to be torn from the top and peeled from the vial prior to use. This closed embodiment of an aluminum cap has several disadvantages. First, the tearing of the metal cap creates sharp edges which may cut or damage sterile gloves and cut the person administering the drug, thereby exposing both the healthcare worker and the patient to disease and contamination of the drug. Second, the tearing of the aluminum cap generates metal particles which may also contaminate the drug. The dangers associated with the tearing of an aluminum cap has been solved in part by adding a "flip-off" plastic cap. In one such embodiment, the aluminum collar includes a central opening and a shallow plastic cup-shaped cap is received over the aluminum collar having a central projecting riveting portion which is received and secured in the central opening of the aluminum collar. The plastic cap is then removed by forcing the flip-off cap away from the aluminum collar, which tears an annular serrated portion surrounding the central opening and exposes an opening in the collar for receipt of a hypodermic needle or the like. This

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embodiment reduces but does not eliminate the possibility of tearing the sterile gloves of the healthcare worker. More importantly, however, aluminum dust is still created which may contaminate the medicament. It is also important to note that metallic dust is also created simply by forming and affixing the aluminum collar to the vial because aluminum dust is created in forming the aluminum collar, crimping of the collar and removal of the flip-off plastic cap.

Aluminum collars have also been used to secure a fluid transferset on medicament vials. Transfersets may be utilized, for example, to transfer fluid from a syringe to a vial; such as to reconstitute a dry or powdered drug in a vial by adding a diluent or solvent. The reconstituted drug may then be withdrawn from the vial by the syringe. The inner surface of the transferset may be part of the drug fluid path and the aluminum collar or ring may bring aluminum particles in the sterile room where the drug is added to the vial or into the drug fluid path contaminating the drug. There have been attempts to reduce this problem by applying a coating to the aluminum cap or collar. Finally, the prior art also includes snap-on cup-shaped plastic caps or collars having a radially inwardly projecting end portion which is snapped over the rim portion of the vial. Snap-on plastic collars, however, do not assure adequate sealing of the vial or fully accommodate the tolerances of standard vials and stoppers as required.

The need therefore remains for a closure for vials and other medical containers which may be utilized with conventional containers, such as medicament vials or cartridges, which assures sealing of the container and which achieves a good level of cleanliness, without metal particles or dust which may contaminate the medicament, the transferset or the clean room and which does not expose the healthcare worker to sharp metal edges. The plastic closure of this invention solves these problems and permits the use of the plastic closure of this invention for attaching and sealing containers and fluid transfersets as described below.

### SUMMARY OF THE INVENTION

As set forth above, the plastic closure for sealing a vial or other medical container of this invention eliminates the problems associated with a malleable metal or aluminum cap or collar, but which accommodates the buildup of tolerances of the rim portion of the container and the elastomeric stopper, when used. The plastic closure of this invention is relatively inexpensive to manufacture and use. The plastic closure of this invention may be utilized as a cap to seal a conventional medicament vial, as a collar in combination with a flip-off cap or as a collar used to secure and seal a transferset on a vial for transferring fluid between a vial or other container and a second container. As used herein, the term closure is generic to either a cap or collar.

As stated, the plastic closure for sealing a container of this invention may be utilized with a conventional vial having an open end and a reduced diameter neck portion adjacent the open end. The plastic closure of this invention includes a generally tubular portion and a portion which is deformed radially or crimped into the reduced diameter portion of the container to retain the closure on the container and as a cap to seal the open end of the container. The plastic closure of this invention may also be used as a cap or collar with a conventional vial and elastomeric stopper. In the preferred embodiment, the plastic closure of this invention is formed of a polymer which is sufficiently malleable to permit radial deformation, yet sufficiently rigid to retain its shape following deformation and sufficiently resistant to creep to main-

tain the seal between the plastic cap and the container following radial deformation.

The preferred embodiment of the plastic closure of this invention is formed of a polymer alloy or melt blend which includes a relatively tough soft malleable copolymer and a relatively rigid polymer. In the most preferred embodiment of the plastic closure of this invention, the composite polymer is a polymer alloy of a relatively soft malleable co-polymer and a relatively rigid polymer. The preferred relatively rigid polymer is a polyamid or a polycarbonate and the preferred relatively soft co-polymer may be selected from polyesters or polyolefins. The resultant polymer alloy or composite preferably has an elongation at yield between 5% and 10% and an elongation at break greater than 100% with a flexural modulus of greater than 1900 MPa.

Where the container includes a radial rim portion adjacent the open end, the plastic closure of this invention includes a generally cylindrical tubular portion preferably having an internal diameter generally equal to or slightly greater than the external diameter of the rim portion of the container adapted to be received over the rim portion of the container having a free distal end adapted to be deformed radially inwardly or crimped beneath the rim portion of the container and sealed relation. The plastic cap or collar of this invention may also include a radially inwardly projecting proximate portion which overlies the rim portion of the container and/or the stopper. This radial portion may be closed or more preferably includes a central opening which may be closed with a flip-off or peel-off type plastic closure or seal. In the preferred embodiment, the peel-off seal includes a looped end portion which is welded or glued to the tubular portion surrounding the transferset providing indication of tampering and a free end which may be gripped to remove the seal.

Where the plastic collar of this invention is utilized to secure a transferset for transferring fluid from the container to a second container, the preferred embodiment of the collar includes a second tubular portion which at least partially surrounds the internal components of the transferset. In one preferred embodiment, the second tubular portion completely surrounds the internal components of the transferset, which may have a closed end integral with the second tubular portion or closed with a sealing member. In the most preferred embodiment, the collar portion is integral with the tubular portion surrounding the transferset and the tubular fluid transfer portion such that the major components of the transferset may be molded in one piece. In another embodiment, the transferset includes a cup-shaped cap which is received over the second tubular portion of the collar. In the preferred embodiments of the plastic collar of this invention which secures or is integral with a transferset attached to the container, the internal surface of the tubular portion which surrounds the rim of the container includes an annular resilient ring which is biased against the rim portion of the container to prevent rotation of the collar and transferset on the vial. In one preferred embodiment, the internal surface of this tubular portion includes an annular groove adjacent the free end of the tubular portion and the annular resilient ring is received and retained in the annular groove. The preferred embodiment of the plastic closure of this invention may also be formed of a relatively clear polymer or polymer alloy which maintains its clarity under the stress of deformation which is particularly advantageous where the plastic closure of this invention is utilized as a collar to secure and seal a transferset on the container.

The method of this invention then includes forming a plastic closure having a generally cylindrical tubular portion having an internal diameter generally equal to or slightly

greater than an outside diameter of the rim portion of the container and an integral radial rim portion, disposing the closure over the rim of the container with the radial rim portion overlying the rim portion of the vial and the tubular portion surrounding the container rim, and then radially permanently deforming or crimping the free end of the tubular portion of the collar into the neck portion of the container, beneath the rim portion, permanently securing the closure on the container and sealing the container open end.

In the most preferred embodiment of the method of this invention, the plastic closure of this invention is formed by injection molding the plastic closure from a polymeric alloy or composite having a relatively soft malleable polymer or co-polymer and a relatively rigid polymer, wherein a polymeric alloy or composite is formed during the injection molding. Where a resilient or polymeric ring is utilized to prevent rotation of the closure on the container, the ring may be co-injected with the polymer forming the closure or an annular groove may be formed in the tubular portion of the closure, adjacent the free end. The method then includes inserting the annular resilient ring in the groove prior to radial permanent deformation of the free end of the closure as described, such that the resilient ring is biased against the rim portion of the container. A thermoplastic elastomer may also be co-injected with the polymer forming the closure to form a coating or film on the inside surface of the closure which is integrally bonded to the polymer of the cap.

The plastic closure of this invention may be utilized with a vial or other medical container having a conventional elastomeric stopper or as a collar in combination with a transferset having a sealing member as disclosed in the prior art or more preferably the collar portion may be formed integral with components of the transferset. Where the plastic closure of this invention is used to seal a container having an elastomeric stopper, the proximate radial lip of the closure is received over and preferably biased against the resilient radial lip of the stopper during radial deformation or crimping of the free of the tubular portion of the closure beneath the rim of the container. The plastic closure of this invention thus eliminates the problems associated with malleable metal collars or caps, such as aluminum, and is relatively inexpensive, and simple to manufacture, particularly when compared with aluminum caps having a protective coating. The plastic closure of this invention assures an excellent seal of the container and can be injection molded in a clean environment or washed, if necessary. Finally, the plastic closure of this invention accommodates the tolerances of the vial and particularly the buildup of tolerance variations in the combination of a conventional vial and elastomeric stopper. Other advantages and meritorious features of the present invention will be more fully understood from the following description of the preferred embodiments, the appended claims and the drawings, a brief description of which follows.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side cross-sectional view of one preferred embodiment of the plastic closure of this invention secured to and sealing a conventional vial having an elastomeric stopper;

FIG. 2 is an exploded side cross-sectional view of the open end of a conventional vial, elastomeric stopper and the plastic closure shown in FIG. 1 prior to radial deformation of the free end of the closure;

FIG. 3 is a side partially cross-sectioned view of the assembly shown in FIG. 1 illustrating radial deformation or crimping of the closure;

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FIG. 4 is a partial side view of an alternative embodiment of the plastic closure of this invention assembled on a vial or other container;

FIG. 5 is a top cross-sectional view of FIG. 4 in the direction of view-arrows 5—5;

FIG. 6 is a side view of a vial and transferset assembly having the plastic collar of this invention;

FIG. 7 is a partial side cross-sectional view of an alternative embodiment of the vial and transferset assembly;

FIG. 8 is a partial side cross-sectional view of the vial, collar and transferset assembly similar to FIG. 7 of an alternative embodiment of this invention;

FIG. 9 is a partial side cross-sectional view of a vial, stopper and transferset assembly of this invention;

FIG. 10 is a partial side cross-sectional view illustrating a further alternative embodiment of the vial and transferset assembly of this invention;

FIG. 11 is a side cross-sectional view of an embodiment of a collar and transferset assembly similar to FIG. 9 which has been simplified to reduce costs; and

FIG. 12 is top perspective view of the transferset shown in FIG. 11 illustrating a preferred embodiment of the peel-off seal.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1 to 3 illustrate one preferred embodiment of the vial, stopper and cap assembly 20 of this invention. As set forth above, the closure of this invention may be utilized to seal various containers and is particularly useful for sealing medicament containers such as the conventional vial 22 illustrated in FIGS. 1 to 3. The vial includes an open end 24, an annular radially extending rim portion 26 and a neck portion 28 adjacent the rim portion. As best shown in FIGS. 9 and 10, the neck portion 28 of the vial has a reduced diameter when compared to the rim portion 26 and the container portion 30. The internal surface 31 of the vial adjacent the open end 24 is generally cylindrical. Medicament vials of this type are generally formed of glass or a sterilizable plastic. The open end 24 of the vial is typically closed with an elastomeric stopper 32 having a tubular body portion 34 which is received in the open end 24 of the vial and a planar rim portion 36 which overlies the rim portion 26 of the vial as shown in FIG. 1. The stopper is generally formed of a resilient elastomeric material such as synthetic or natural rubber. The central portion 38 of the planar rim portion 36 may be pierced with a hypodermic needle, for example, to either withdraw fluid from the vial or add a solvent or diluent to the vial where the medicament in the vial is a dry or powder drug. The tubular portion 34 of the stopper has an external diameter generally greater than the internal diameter of the internal cylindrical surface 31 of the vial to provide a tight or interference fit.

One preferred embodiment of the closure 40 is shown in FIG. 1 attached to a vial 22 and stopper 32 assembly, prior to assembly in FIG. 2 and during assembly in FIG. 3. This embodiment of the collar 40 includes a tubular portion 42 which surrounds the rim portion 26 of the vial and the planar rim portion 36 of the stopper. Where the external surface of the rim portion 26 of the vial is cylindrical, the tubular portion 42 of the collar will generally also be cylindrical. As shown in FIG. 1, the free end 44 of the tubular portion 42 is deformed inwardly or crimped beneath the adjacent surface of the rim portion 26 of the vial, permanently securing the collar 40 on the vial and sealing the vial. This embodiment

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of the collar 40 also includes an integral radial proximate portion 46 which overlies the rim portions 26 and 36 of the vial and stopper, respectively. The radial portion 46 is preferably integral with the tubular portion 42 of the collar. This embodiment of die collar 40 also includes a central opening 48 which overlies the central portion 38 of the stopper, preferably coaxially aligned with the central portion of the stopper. As described below, however, the central opening 48 may be eliminated in certain applications of this invention. As used herein, the terms proximate and distal are used solely for ease of description, wherein the term proximate refers to elements or portions of elements closest to the rim portion 36 of the stopper and distal refers to elements or portions of elements more remote from the rim portion of the stopper. Further, the terms cap and collar are sometimes used herein interchangeably. The term cap, however, generally refers to a closure having a radial portion which overlies the container opening and collar is used to refer to a closure used to secure an element, such as a transferset, to the container.

In this disclosed embodiment, the collar 40 includes a shallow cup-shaped cap 50. In the disclosed embodiment, the cap 50 includes a tubular portion 52 which surrounds the proximate portion of the tubular portion 42 of the collar, an integral central radial bridging portion 54 and a plurality of U-shaped tabs which, in the disclosed embodiment, are integral with the central bridging portion 54. The U-shaped tabs 56 are received through the central opening 48 of the collar and snap in place to securely retain the cap 50 on the collar 40. As shown in FIG. 2, the cap 50 may be preassembled on the collar 40 prior to assembly of the collar on the vial. The tabs 56 may also be separate members or the central portion of the cap 50 including the tabs 56 may be a separate member.

The collar 40 is then assembled on the vial 22 as shown in FIG. 2. In a typical application, the tubular portion 34 of the stopper is first inserted into the opening 24 of the vial 22 generally after the vial is filled. As set forth above, the plastic collar 40 of this invention may be used with various containers including conventional medicament vials as shown. Thus, in a typical application, the vial 22 will first be filled with a medicament. The tubular portion 42 of the collar 40 is then received over the rim portion 36 of the stopper and the rim portion 26 of the vial as shown in FIG. 3. The free end 44 (shown before deformation in phantom in FIG. 3) is then deformed radially beneath the radial rim 26 of the vial by a suitable tool, such as the crimping tool 58 shown in FIG. 3. The disclosed embodiment of the crimping tool includes a conical rim 60 which deforms or crimps the free end 44 of the collar beneath the rim 26 of the vial. In a typical application, the tool 58 is rotated around the rim 26 of the collar 40, deforming or crimping the free end 44 as shown in FIGS. 1 and 3. In certain applications, it may be desirable to heat either the free end 44 of the collar or the tool 58 to facilitate crimping. The sealed vial may now be stored for later use.

When the vial is ready for use, the cap 50 may be removed simply by forcing one side of the cap 50 upwardly away from the collar 40, removing the cap 50 from the collar 40 and exposing the central opening 48 of the collar and the central portion 38 of the stopper. The central portion 38 of the stopper may then be pierced with a conventional hypodermic needle, for example, providing access to the container portion 30 of the vial. Where the material of the cap 50 is selected to provide resiliency, such as polyethylene or polypropylene, the tabs 56 will bend under thumb pressure, permitting easy removal of the closure 50. Alternatively, where the material of the cap is relatively rigid, at least some

of the tabs 56 will break also permitting removal of the cap. It should also be noted that the radial portion 46 of the collar is preferably compressed against the resilient rim portion 32 of the elastomeric stopper during radial deformation of the free end 44 of the collar to assure a secure seal of the vial following installation. The tabs 56 are thus compressed into the radial rim 32 of the stopper as shown in FIG. 1.

The polymer selected for the plastic closure of this invention can best be described by its required physical properties. The polymer must be sufficiently malleable to permit radial deformation or crimping, yet sufficiently rigid to retain its shape following deformation. The polymer must also be sufficiently resistant to creep to maintain the seal between the plastic cap and the container following radial deformation. It has been found that a polymer having an elongation at yield between 5% and 10% and an elongation at break greater than 100%, combined with a flexural modulus of greater than 1,900 MPa has superior performance. Where the plastic closure of this invention is utilized for sealing vials containing a medicament, the polymer should also be sterilizable and, in certain applications such as the plastic collar for a vial transferset described below, the polymer is preferably relatively clear and maintains its clarity under the stress of deformation or crimping. It has been found that certain polymer alloys or composite polymers including melt blends or alloys and co-polymers having polymers of different malleability and rigidity are preferred in many applications. That is, the plastic closure of this invention is preferably formed of a polymer alloy, composite polymer or co-polymer including a relatively rigid polymer and a tough relatively soft malleable co-polymer. The most preferred polymer is a polymer alloy or melt blend including a polyamid or polycarbonate as the rigid polymer providing the strength and resistance to creep desired for this application. The relatively soft malleable co-polymer may be selected from various polymers including polyesters and polyolefins; however, a polymer alloy including a polycarbonate or polyamid and a polyester has been found particularly suitable for this application.

As will be understood, various polymeric melt blends, alloys, composites and co-polymers are being developed on a rapidly increasing basis and therefore the plastic collar of this invention is not limited to a specific polymer, provided the polymer has the desired physical properties described above. Suitable polymers for the plastic collar of this invention include EASTAR® MB polymers, which are melt blend and alloy polymers and EASTAR® thermoplastic polymers, which are neat polymers sold by Eastman Chemical Company of Kingsport, Tenn. and Eastman Chemical AG of Zug, Switzerland under the trade names "DA003, DN003" and "DN004". These materials are polymer melt blends, alloys and co-polymers of polycarbonate or polyamid and polyester. As used herein, the terms melt blends and alloys refer to polymeric compositions having two or more polymers of different physical properties or characteristics, such as the EASTAR® polymers of Eastman Chemical Company described above which include a polycarbonate or polyamid and a polyester. The polymer selected for the plastic collar of this invention may also include fillers and other constituents which would be more accurately described as a composite. Although the base polymers may still be a polymeric melt blend or alloy. As used herein, the term composite is used in its broadest sense to include alloys or melt blends, composites and co-polymers. As will be understood, the manufacturer or supplier of the raw material will normally blend the polymers based upon the specifications of the customer. The polymers may be co-injected to form a

polymeric melt blend, alloy or composite or formed by any other suitable processes. It is anticipated, however, that other polymers having the described physical characteristics may also be utilized in the plastic collar or cap of this invention. In certain applications, it may also be desirable to coat at least the interior surface 43 of the collar shown in FIG. 2 with a thermoplastic elastomer, or the entire collar may have a thin layer of a thermoplastic elastomer. The thermoplastic elastomer coating may be applied as a film or by co-injection with the polymer forming the collar 40. The collar 40 and the closure 50 may be formed by conventional injection molding processes.

The plastic collar 140 of the vial, stopper and collar assembly 120 shown in FIGS. 4 and 5 may be identical to the collar 40 shown in FIGS. 1 to 3 except that the collar 140 includes a plurality of ribs 162 which provide an improved finger gripping surface for removal of the cap or closure 50. The vial 22, elastomeric stopper 32 and the cap or closure 50 are identical to the same elements in FIGS. 1 to 3 and are therefore numbered the same. The collar 140 is numbered in the same numerical sequence as the collar 40 in FIGS. 1 to 3 for ease of reference. As described above, the cap or closure 50 may be eliminated in certain applications in either embodiment by either providing an integral frangible central portion or by applying a peel-off seal of paper, plastic, aluminum or foil over the radial portion 46 adjacent the central opening 48 having a suitable adhesive providing a microbio barrier sealing the central opening 48.

FIG. 6 illustrates one embodiment of the plastic collar or cap 240 of this invention mounted on a conventional vial 22 having a container portion 30 utilized to secure a fluid transferset 250. The plastic collar 240 of this invention may be utilized to secure any fluid transferset to a suitable container, such as the conventional vial 22 shown in FIG. 6 including but not limited to the fluid transferset disclosed in co-pending application Ser. No. 09/031,302 filed Feb. 26, 1998, the disclosure of which is incorporated herein by reference. The plastic collar 240 of this invention includes a tubular portion 242 and a free distal end 244 which is deformed radially or crimped beneath the rim portion 26 of the vial 22 as described above and shown in FIGS. 7 and 8. In the embodiment of the vial and transferset assembly 220 shown in FIG. 6, the collar includes a radial portion 246 and a second tubular portion 248 integral with the radial portion 246 having a diameter less than the tubular portion 242. In this embodiment, the fluid transferset 250 includes a cup-shaped cap or closure 252 having a proximate radial portion 250 as shown in FIGS. 7 and 8 which is received between the radial portion 246 of the collar which overlies the rim portions of the elastomeric stopper and the vial secured in place by the plastic collar 240.

FIGS. 7 and 8 illustrate alternative embodiments of the collar assembly shown in FIG. 6 which include an elastomeric or rubber element limiting rotation of the collar on the vial. In the embodiment of the collar 240 shown in FIG. 7, the distal free end 244 of the tubular portion 242 includes a groove 264 in the internal surface 243 which receives a rubber or an elastomeric O-ring 268. Thus, when the free end 244 is deformed radially inwardly or crimped against the underside of the rim portion 26 of the vial, the O-ring 268 is resiliently deformed against the rim portion 26 providing torque resistance to turning of the collar 240 relative to the vial. In one embodiment of the fluid transferset, the cap 252 is removed prior to use by twisting the cap which is provided with a frangible portion 270 formed by the V-shaped groove 272 located beneath the tubular portion 248. The frangible connection between the

distal portion of the cup-shaped cap 248 and the proximate portion including the radial flange 252 may take various forms, including, for example, a V-shaped continuous or discontinuous groove in the inner or outer wall of the cap. Thus, it is desirable to increase the torque required to turn the collar 240 relative to the vial which is provided by the O-ring 268. In addition, the O-ring provides an additional seal preventing contamination of the space between the collar and the vial. Thus, the O-ring 268 or the seal disclosed in FIG. 8 may be added to the embodiments of the plastic collar shown in FIGS. 1 and 4. In the embodiment of the collar assembly 340 shown in FIG. 8, the O-ring has been replaced with an annular sealing member 368 which, in the disclosed embodiment, is flat or generally rectangular. The annular sealing member 368 shown in FIG. 8 may be formed of a suitable elastomeric material, such as natural or synthetic rubber, which is co-injected with the polymer forming the collar 240 or 340 or secured to the internal surface 243 or 343 of the free end 244 or 344 of the tubular portion of the collar by a suitable adhesive. The common elements of the vial, stopper and transferset shown in FIGS. 6, 7 and 8 are numbered the same and the collar 240 and 340 are numbered in the same numerical sequence for ease of reference.

FIGS. 9 and 10 illustrate alternative embodiments of the plastic collar of this invention utilized to secure a vial transferset as described more fully in the above-referenced co-pending patent application, wherein the plastic collar forms a part or component of the transferset. Again, the vial 22 may be identical to the medicament vial described above or other suitable container. The elastomeric stopper 32 may be identical to the elastomeric stopper described above except that in this embodiment, the tubular portion 34 of the stopper includes conventional axial slots 35 which permit freeze drying of liquid in the vial 22.

The components of the vial fluid transferset disclosed in the above-referenced patent application need not be described herein in detail. Briefly, the fluid transfer assembly or transferset 462 includes a tubular transfer member 464 and a piercing member 466. The tubular transfer member 464 includes a Luer connection 468 which in the disclosed embodiment are male threads on the exterior surface of the tubular transfer member. The piercing member 466 includes a pointed piercing end 470 and an external channel 472 which, in the disclosed embodiment, extends from adjacent the piercing end 470 to the body or barrel portion 473. The external channel 472 may be continuous and extend longitudinally as shown or extend spirally or be discontinuous. The tubular transfer member 464 includes a proximate internal surface 474 and a distal internal surface 475 having a diameter less than the internal diameter of the proximate internal surface 474 to define a lip 476 which receives the radial flange 478 of the piercing member 466, such that the piercing member 466 is retained in the tubular transfer member 466 for telescopic movement of the piercing member toward the central portion 38 of the elastomeric stopper 32. The proximate end of the tubular transfer member 464 in the disclosed embodiment includes a relatively sharp edge 480 which is pressed into the central portion 38 of the elastomeric stopper during assembly as described below and includes an integral outer tubular portion 482 having a radial lip 484 which includes an annular barb 486 which is pressed into the radial rim portion 36 of the stopper.

The plastic collar 440 of this embodiment of the invention includes a tubular portion 442 which surrounds the planar rim portion 36 of the stopper and the radial rim 26 of the vial. In this embodiment, however, the internal surface of the

tubular portion 442 has a plurality of longitudinal ribs 443 which engage the planar portion 36 of the stopper and the rim 26 of the container and retains the collar on the container following preassembly. In the disclosed embodiment, the collar includes three ribs 443 spaced equally along the tubular portion 442; however, the number may be varied as desired. The free end 444 is deformed radially inwardly or crimped around the rim portion 26 of the vial as described above which includes an elastomeric O-ring 488 which limits rotation of the collar 440 on the vial 22. The collar 440 further includes a radial portion 490 integral with the tubular portion 442 which overlies the rim portions 36 and 26 of the elastomeric stopper and vial, respectively and 484 of the transferset 462. The collar 440 further includes a tubular portion which is integral with the radial portion 490, which surrounds the transferset 462. In this embodiment, the distal tubular portion 496 has an internal diameter greater than the internal diameter of the proximate tubular portion 494 to more easily accommodate receipt of a syringe or intravenous (IV) set connector during use of the transferset. In the disclosed embodiment, the distal end of the collar includes a radial flange 498 and the distal open end of the collar is sealed with a peel-off seal 500 formed of paper, plastic, aluminum or foil which is adhesively bonded to the radial flange portion 498 providing easy access to the transferset 462.

The plastic collar and transferset assembly of this invention shown in FIG. 9 may be utilized to transfer fluid between the vial 22 or other suitable container and a conventional syringe, intravenous set or the like. The seal is removed by removing the peel-off seal 500 which provides access to the transferset 462. A conventional syringe (not shown) having a female Luer Lock connector, for example, may be threaded on the male Luer Lock connector 468. As the Luer connectors of the tubular transfer member 464 and syringe are threaded together, the, nozzle portion of the syringe is received in the tubular transfer member which simultaneously drives the piercing end 470 of the piercing member 466 through the central portion 38 of the elastomeric stopper providing fluid communication between the vial 22 and the interior of the tubular transfer member 464 through external channel 472. In a typical application, drugs in a dry or powdered form may be stored in the vial 22 to increase the shelf life of the drug. The syringe may be utilized to transfer a diluent or solvent into the vial to reconstitute the drug which may then be withdrawn into the syringe for application to a patient.

FIG. 10 illustrates a further alternative embodiment of the plastic collar and transferset of this invention wherein the entire cap is removable. The transferset 462 including the tubular transfer member 464 and piercing member 466 may be identical to the transferset disclosed in FIG. 9. Further, the vial 22 and elastomeric stopper 32 are conventional as shown in FIG. 9.

The embodiment of the plastic collar 540 shown in FIG. 10 includes a tubular portion 542 which surrounds the planar rim portion 36 of the stopper having internal longitudinal spaced ribs 543 which receives the rim portion 26 of the vial to assure preassembly of the components on the vial prior to crimping. The free end 544 of the collar is deformed radially or crimped beneath the rim portion 26 of the stopper as described above. The internal surface of the free end 544 of the collar further includes an elastomeric O-ring 488 as described above which is resiliently deformed against the rim portion 26 of the vial preventing rotation of the collar on the vial. In this embodiment of the plastic collar 540, the radial portion 546 overlies the radial portion 484 of the

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tubular transfer member and the tubular portion 548 is spaced inwardly from the tubular portion 542 to receive a cup-shaped cap 550. As shown, the cup-shaped cap 550 includes a cylindrical proximate portion 552, a conical portion 554 and a closed end portion 556. In this embodiment, the cap 550 is secured to the plastic collar 540 by a twist-off preslit label 560 made of plastic, aluminum or foil which provides evidence of tampering. The cap 550 may then be easily removed by breaking or rupturing the seal 560 providing access to the transferset 462.

The plastic collar 640 as shown in FIG. 11 is similar to the collar and transferset assembly shown in FIG. 9 except that the tubular transfer member 664 is formed integral with the outer tubular portion 682 thereby simplifying the design and permitting molding of these parts of the transferset in one piece, which also simplifies assembly and reduces the cost. The components of the integral collar and transferset assembly of FIG. 11 has been numbered where practical in the same sequence as the collar and transferset assembly of FIG. 9. Briefly, the transferset 662 includes a tubular transfer member or portion 664 and a piercing member 466 which in this embodiment is identical to the piercing member 466 shown in FIG. 9 and described above. The tubular member 664 includes a Luer Lock connection 668 which in the disclosed embodiment are male threads on the exterior surface of the tubular transfer member. As described above, the tubular transfer member or portion 664 includes a proximate internal surface 674 and a distal internal surface 675 having a diameter less than the internal diameter of the proximate internal surface 764 to define a lip 676 which receives the radial flange 478 of the piercing member 466, such that the piercing member 466 is retained in the tubular transfer portion 664 for telescopic movement of the piercing member toward the central portion 638 of the stopper 632. In this embodiment, the elastomeric stopper 632 includes a planar portion 636 which is received on the rim 26 of the vial 22 as described above; however, in this embodiment of the stopper 632, which is also conventional, the generally tubular portion 634 which extends into the internal surface 31 of the vial is thicker and the internal surface is arcuate defining an arcuate central portion 638 which receives the piercing end 470 of the piercing member 466.

The proximate end of the tubular transfer portion 664 in the disclosed embodiment also includes a relatively sharp edge 680 which is pressed into the central portion 638 of the elastomeric stopper during assembly as described above. The plastic collar 640 of this embodiment includes a tubular portion 642 which surrounds the planar rim 636 of the elastomeric stopper and the radial rim 26 of the vial. In this embodiment, however, the internal surface of the tubular portion 642 and the radial portion 684 includes a plurality of spaced ribs 643 which are pressed into the planar portion 636 of the elastomeric stopper, preventing rotation of the collar 640 and transferset on the vial. As described above, the integral collar and transferset is permanently secured to the vial by permanently radially deforming the free end 644 inwardly around the rim portion 26 of the vial which includes an elastomeric O-ring 688 which also limits rotation of the collar 640 on the vial 22 and an additional seal of the assembly. The outer tubular portion 682 is formed integral with the tubular transfer portion 664 by an integral radial annular web 670 forming a rigid assembly which is simpler in design and less costly as described above. The radial portion 684 of the outer tubular portions 682 includes an annular barb 686 having the same function as the barb 486 described above. Other details of the preferred embodiment of the integral collar and transferset assembly shown in

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FIG. 11 will be understood from the description above. As will be understood by those skilled in the art, however, the integral design of the collar 640, outer tubular member 682 and the tubular transfer member 664 may be injection molded in one piece forming a relatively rigid structure which eliminates assembly of the individual components and reduces costs.

The peel-off seal 600 shown in FIGS. 11 and 12 seals the internal components of the transferset 662, may be easily removed and provides an indication of tampering. The disclosed embodiment of the seal 600 includes a sealing portion 602 which in the disclosed embodiment is circular to accommodate the shape of a conventional vial and may be formed of paper, plastic, aluminum or foil which is adhesively bonded to the radial flange portion 698 of the outer tubular portions 682 as described above. This embodiment, however, includes an integral tab 604 including a central portion 606 which is welded or adhesively bonded to the outer tubular portion 682 of the transferset by glue 608. Securing the central portion 606 of the seal to the transferset prevents inadvertent removal of the seal and evidence of tampering. The free end 610 of the tab may be easily gripped for peeling off the seal 600 from the transferset.

As described in regard to the embodiments of the plastic cap shown in FIGS. 1 to 5, the plastic collar 440 in FIG. 9, 546 in FIG. 10 and 640 in FIG. 11 are preferably secured to the vial 22 by compressing the radial portion 490 in FIG. 9, 546 in FIG. 10 or 684 in FIG. 11 against the resilient planar portion of the stopper. In the embodiments shown in FIGS. 9 and 10, the radial portion 490 in FIG. 9 or 546 in FIG. 10 is compressed against the radial portion 484 of the tubular transfer member, which compresses the radial portion and the annular barb 486 against the resilient planar rim portion 36 of the elastomeric stopper during radial deformation of the free end 444 in FIG. 9 and 544 in FIG. 10 of the collar beneath the rim 26 of the vial, thereby sealing the vial and securing the collar to the vial. In the simplified embodiment of the integral collar and transferset shown in FIG. 11, the radial portion 684 of the outer tubular portion 682 of the transferset is compressed directly against the planar portion 636 of the resilient elastomeric stopper, which compresses the annular barb 686 against the planar rim portion 636 of the stopper during radial deformation of the free end 644 of the collar portion 640 forming a tight seal. The plastic collar 440 and the integral outer tubular portion 494 in FIG. 9, 540 in FIG. 10 and the integral collar 640, outer tubular portion 682 and tubular transfer portion 664 are preferably formed of a polymer having the physical properties and characteristics described above, thereby permitting crimping of the collar on a vial or other container. More preferably, the plastic collar is formed of a polymeric melt blend or alloy including a tough relatively soft malleable polymer and a relatively rigid polymer and most preferably a polymeric alloy including polycarbonate and polyester. As will be understood, however, various modifications may be made to the plastic closure of this invention within the purview of the appended claims.

What is claimed is:

1. A sealed medical container and transferset assembly, said medical container having an open end, a rim portion surrounding said open end, a neck portion adjacent said rim portion having a diameter smaller than said rim portion, and a pierceable closure located in said open end of said medical container; said transferset comprising:

an integral generally tubular polymeric collar member having a first tubular portion surrounding said rim portion of said medical container including a free end

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permanently deformed radially inwardly into said neck portion and permanently securing said collar member to said medical container, a radial portion overlying said rim portion of said medical container and supported by said medical container rim portion and a second tubular portion generally coaxially aligned with said first tubular portion extending from said rim portion of said medical container and coaxially aligned with said open end of said medical container having an open end, said integral tubular polymeric collar member formed of a polymer which is sufficiently malleable to permit radial deformation, yet sufficiently rigid to retain its shape following deformation and sufficiently resistant to creep to maintain a seal between said collar and said medical container;

a closure overlying said open end of said second tubular portion of said collar member and secured thereto in sealed relation; and

a piercing member telescopically supported within said second tubular portion and moveable relative to said second tubular portion to pierce said pierceable closure in said open end of said medical container to provide fluid communication between said medical container and said transferset.

2. The sealed medical container and transferset assembly defined in claim 1, wherein said transferset further includes a tubular transfer member located within said second tubular portion of said collar member coaxially aligned with said open end of said sealable closure of said medical container sealingly engaging said sealable closure and telescopically receiving said piercing member.

3. The sealed medical container and transferset defined in claim 2, wherein said tubular transfer member is integral with said second tubular portion of said collar member.

4. The sealed medical container and transferset assembly defined in claim 2, wherein said tubular transfer member includes a free distal open end having a Luer Lock connector for receipt of a Luer Lock connector of a second container.

5. The sealed medical container and transferset assembly defined in claim 1, wherein said polymeric collar member is formed of a polyamid polymer or a composite polymer including a relatively soft malleable co-polymer and a relatively rigid polymer.

6. The sealed medical container and transferset assembly defined in claim 1, wherein said free end of said first tubular portion includes an annular resilient ring retained on an internal surface of said collar member adjacent said free end biased against said medical container rim portion and preventing rotation of said collar member on said medical container.

7. A sealed vial and transferset assembly comprising a vial having an open end, a radial rich portion surrounding said open end and a reduced diameter neck portion adjacent said rim portion and a pierceable closure located with said vial open end sealing said vial, and a transferset mounted on said vial open end of said vial for transferring fluid between said vial and a container, said transferset including a tubular transfer member having a first open end engaging said pierceable closure in sealed relation and a second open end, a piercing member reciprocally supported within said tubular transfer member and moveable relative to said tubular transfer member to pierce said pierceable closure and establish fluid communication between said vial and said tubular transfer member, and a plastic collar having first a tubular portion surrounding said rim portion of said vial having a free end permanently deformed radially inwardly into said vial neck portion permanently retaining said collar on said vial and a

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second integral tubular portion surrounding said tubular transfer member having an open end and a closure closing said open end of said second tubular portion of said collar, said plastic collar formed of a polymer which is sufficiently malleable to permit radial deformation, yet sufficiently rigid to retain its shape following deformation and sufficiently resistant to creep to maintain the seal between said collar and said vial following deformation.

8. The sealed vial and transferset assembly defined in claim 7, wherein said plastic collar is formed of a polyamid polymer or a composite polymer including a relatively soft malleable co-polymer and a relatively rigid polymer.

9. The sealed vial and transferset assembly defined in claim 8, wherein said plastic collar is formed of a polymer alloy comprising a relatively soft malleable co-polymer and polycarbonate as said relatively rigid polymer.

10. The sealed vial and transferset assembly defined in claim 7, wherein said tubular portion of said plastic collar includes an annular resilient ring retained on an internal surface of said collar adjacent said free end biased against said vial radial rim portion and preventing rotation of said collar on said vial.

11. The sealed vial and transferset assembly defined in claim 10, wherein said internal surface of said tubular portion includes an annular groove adjacent said free end and said resilient ring is received and retained in said annular groove.

12. The sealed vial and transferset assembly defined in claim 7, wherein said tubular portion of said plastic collar includes an elastomeric coating on an internal surface thereof integrally bonded to said internal surface.

13. The sealed vial and transferset assembly as defined in claim 7, wherein said tubular transfer member is integral with said plastic collar.

14. The sealed vial and transferset assembly as defined in claim 13, wherein said tubular transfer member is integrally joined to said second tubular portion of said collar in coaxial spaced relation by an integral radial web portion.

15. The sealed vial and transferset assembly as defined in claim 13, wherein said plastic collar includes an integral radial portion between said first and second integral tubular portions overlying said pierceable closure of said vial and engaging said pierceable closure in sealed relation.

16. The sealed vial and transferset assembly as defined in claim 7, wherein said plastic collar includes an integral radial portion between said first and second integral tubular portions and said tubular transfer member includes an integral radially outwardly extending portion adjacent said first open end extending between said plastic collar radial portion and said vial open end sealingly engaging said pierceable closure.

17. A sealed medical container and transferset assembly, said medical container having an open end, a rim portion surrounding said open end, a neck portion adjacent said rim portion having a diameter smaller than said rim portion, and a pierceable closure received in said open end of said medical container sealing said container, said transferset comprising:

an integral generally tubular polymeric collar member having a first tubular portion surrounding said rim portion of said medical container including a free end portion permanently deformed radially into said neck portion permanently securing said collar member to said medical container and a second tubular portion generally coaxially aligned with said first tubular portion extending from said rim portion of said medical container having an open end coaxially aligned with said open end of said medical container;

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a tubular transfer member located within said second tubular portion of said collar member coaxially aligned with said open end of said container having a first open end sealingly engaging said pierceable closure and a second open end having a connector portion for attachment to a second medical container; and

a piercing member telescopically supported within said tubular transfer member and moveable relative to said tubular transfer member pierce said pierceable closure and providing fluid communication between said medical container through said tubular transfer member to said second medical container.

18. The sealed medical container and transferset defined in claim 17, wherein said fluid transfer member is integral with said second tubular portion of said collar member.

19. The sealed medical container and transferset assembly as defined in claim 17, wherein said second tubular portion

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of said tubular polymeric collar surrounds said tubular transfer member in generally coaxial spaced alignment and said collar member includes an integral radial portion between said first and second tubular portions supported by said rim portion of said medical container.

20. The sealed medical container and transferset assembly as defined in claim 19, wherein said tubular transfer member is integral with said plastic collar second tubular portion and said radial portion sealingly engages said pierceable closure.

21. The sealed medical container and transferset assembly as defined in claim 19, wherein said tubular transfer member includes an integral radially outwardly extending portion adjacent said first open end extending between said plastic collar radial portion and said vial open end sealingly engaging said pierceable closure.

\* \* \* \* \*

## Recent Significant Rule Makings and Practice Changes

**This two hour training session is mandatory for all patent examiners and managers.** The training will cover recent changes to patent rules and procedures that affect patent examiners.

Training sessions for TCs 2100, 2600, 3600, and 3700 will be held in the Patents Theater (PK2, second floor). There are 18 sessions scheduled. **Please sign up for the earliest date you are available – remember the end of the fiscal year is approaching quickly.** Sessions are scheduled at the following times:

Tuesday, August 10, 2004	1:00-3:00 p.m.
Tuesday, August 17, 2004	1:00-3:00 p.m.
Wednesday, August 18, 2004	9:00-11:00 a.m.
Thursday, August 19, 2004	9:00-11:00 a.m.
Friday, August 20, 2004	9:00-11:00 a.m. and 1:00-3:00 p.m.
Monday, August 23, 2004	1:00-3:00 p.m.
Tuesday, August 24, 2004	1:00-3:00 p.m.
Wednesday, August 25, 2004	9:00-11:00 a.m. and 1:00-3:00 p.m.
Thursday, August 26, 2004	1:00-3:00 p.m.
Monday, August 30, 2004	9:00-11:00 a.m. and 1:00-3:00 p.m.
Tuesday, August 31, 2004	9:00-11:00 a.m. and 1:00-3:00 p.m.
Wednesday, September 1, 2004	9:00-11:00 a.m. and 1:00-3:00 p.m.
Thursday, September 2, 2004	1:00-3:00 p.m.

Registration will be via the Knowledge Management site (<http://ptoweb/patents/km/>).

- Click on **Course Registration**.
- Click on **My Account**.
- Type in your **Employee ID** and **Password** (if you do not know your password, call 703-306-5791 or 703-306-5792 or e-mail AutoTrainR).
- Click on **Login**.
- Click on **Course Description and Schedule**.
- Select **Offering Time** to view classes by date.
- Once you choose a date, click on the arrow at the right end of the box below the date to view all available classes. The arrow is just to the left of the register box.
- Highlight the session you wish to attend (make sure you choose location CPK2-200, there are days where sessions are offered in Crystal City and Alexandria at the same time) and click **Register**.

- Highlight the box for **SPE Assigned** and click **Yes** if you wish to register for this session.

Please contact Automation Registration if you have any questions regarding registration by calling (703) 306-5791 & (703) 306-5792 or e-mailing [AutoTrainR@uspto.gov](mailto:AutoTrainR@uspto.gov).